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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re United States Patent Application of:	)	Docket No.:	2771-657 (7497)
Applicant:	)	Conf. No.:	6762
Application No.:	)	Art Unit:	3761
Date Filed:	)	Examiner:	BIANCO, Patricia
Title:	)	Customer No.:	25559
A CONNECTION HAVING A	)		
LAMINAR FLOW FOR THE	)		
DELIVERY OF A SUBSTANCE	)		

## FACSIMILE TRANSMISSION CERTIFICATE


ATTN: Examiner Patricia BIANCO

Fax No. (571) 273-8300

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Number of Pages (including cover)

  
Steven J. Hultquist

August 30, 2005

Date

RESPONSE TO RESTRICTION REQUIREMENT IMPOSED IN AUGUST 11, 2005  
OFFICE ACTION IN U.S. PATENT APPLICATION NO. 10/665,871

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Sir:

This responds to the August 11, 2005 Office Action in the above-identified application, in which the Examiner imposed a restriction requirement against claims 1-49 pending in the application, between:

- Claims 1-4 and 11-49, drawn to an apparatus and method of using an apparatus having a connector with the membrane defining a chamber for housing the connector, said chamber filled with sterile gas at a higher pressure (Group I); and
- Claims 5-10, drawn to a method for enclosing a connector within a membrane and inserting a gas into the membrane, and sealing the membrane (Group II).

In response, applicant elects Group I claims 1-4 and 11-49. Such election is WITH TRAVERSE.

The traversal is based on the fact that the stated grounds for the restriction do not comport with the requirements of the 35 USC 121, which requires that:

**"[I]f two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions."**

The statute therefore requires as a basis for legally permissible restriction that the subject matter of respective claims be both independent and distinct.

Claim 1 (Group I) is set out below for ease of reference:

**"1. A method comprising: puncturing, with a piercing element of a hollow connector, an opening of a membrane that encloses the hollow connector in a gas that is essentially sterile, wherein puncturing the opening of the membrane generates a laminar flow of the gas along sides of the opening; and transferring the fluids, through the opening with the piercing element of the hollow connector."**

Claim 11 (Group I) recites:

**"11. An apparatus comprising: a hollow connector having an interior wall defining a chamber for the passageway of fluids, wherein the hollow connector comprises a distal end and a proximal end, wherein the distal end is configured to engage a container and the proximal end has an aperture there through for the egress of fluids from the container; and a membrane having an interior surface defining a chamber for housing the hollow connector with a gas that is essentially sterile, wherein the gas has a pressure of greater than about 1 atm inside the membrane."**

Claim 5 (Group II) requires:

**"5. A method comprising: enclosing a connector within a membrane housing; inserting a gas that is essentially sterile into the membrane housing at a gas pressure such that after a piercing element of the connector pierces an opening in the membrane housing, a laminar flow of the gas is generated along sides of the opening; and sealing the membrane housing from an environment external to the membrane housing."**

The examiner has stated at page 2 of the August 11, 2005 Office Action that the subject matter of the respective groups (Group II and Group I) "are related as process of making and product made."

It is apparent from comparison of claims 1, 11 of Group I and claim 5 of Group II that the subject matter of respective groups of claims has as common subject matter an arrangement of (i) a connector, and (ii) a membrane confining a gas and the connector.

The Examiner's attention is directed in this respect to the provisions of MPEP Section 802.01 (Meaning of "Independent" and "Distinct"), which states, inter alia:

**"The term 'independent' (i.e., not dependent) means that there is no disclosed relationship between the two or more subjects disclosed, that is, they are unconnected in design, operation, or effect..."**

It is apparent from this provision of the MPEP that the subject matter of Group I representative claims 1 and 11 and Group II representative claim 5 is not "independent" within the meaning of 35 USC 121 in the respective claims, and that therefore Groups I and II are NOT properly restricted.

Stated another way, it is apparent that the subject matter of the Group I claims and the Group II claims CANNOT BE CHARACTERIZED as being "unconnected in design, operation or effect" (MPEP Section 802.01). The restriction requirement applied against Groups I and III therefore is improper.

The Examiner has given as his reason for restriction an assertion that "[i]n the instant case, the product can be made by another process." This statement concedes the final point that the claimed product can be made by the claimed process, and therefore establishes a substantive connection between the Group II claims directed to the method of making the product, and the Group I claims directed to the product, and under the MPEP criterion quoted above, restriction is improper.

Based on all the foregoing, it is requested that the restriction requirement be withdrawn.

Further, it is pointed out that the subject matter of the respective claims imposes no serious burden of searching on the Examiner, particularly since Group II contains only six claims (claims 5-10).

According to the MPEP section 803:

**"[I]f the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions." MPEP §803.**

Under the applicable criterion of this MPEP provision, the Examiner is required to submit all claims 1-49 to examination on the merits.

### CONCLUSION


Based on the foregoing, the Examiner is requested to reconsider, and on reconsideration to withdraw, the restriction requirement imposed against claims 1-49 in the August 11, 2005 Office Action<sup>1</sup>, and to submit all claims 1-49 to examination on the merits.

If any additional issues remain, the Examiner is requested to contact the undersigned attorney at (919)419-9350 to discuss same, in order that the prosecution of this application is expedited.

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<sup>1</sup> If, despite the compelling basis for withdrawal of the restriction requirement, such restriction requirement is nonetheless maintained and made final, applicant affirmatively requests rejoinder of the method claims 5-10 under the applicable rejoinder provisions of MPEP §821.04 upon confirmation of allowable subject matter in the Group I claims 1-4 and 11-49.

Respectfully submitted,

  
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